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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,234

09/17/2003

Yijun Ruan

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09/29/2009

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

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SUITE 800

WASHINGTON, DC 20005

EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

NOTIFICATION DATE

DELIVERY MODE

09/29/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,234	<b>Applicant(s)</b> RUAN ET AL.	
	<b>Examiner</b> Diana B. Johannsen	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27, 29, 31-50 and 53 is/are pending in the application.
- 4a) Of the above claim(s) 1-24, 42 and 43 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40 and 41 is/are allowed.
- 6) ☒ Claim(s) 25-27, 29, 31-39, 44-50 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0909</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 2, 2009 has been entered.

Claims 25-26, 39-41, 44 and 48 have been amended, and claims 28, 51-52, and 54 have been canceled. Claims 1-24 and 42-43 remain withdrawn (see paragraph 3, below). Claims 25-27, 29, 31-41, 44-50, and 53 remain under consideration herein. Applicant's amendments have necessitated new grounds of rejection that are set forth below.

### ***Rejections withdrawn***

2. In view of applicant's amendments of the claims and the Declaration of Bing Ren under 37 CFR 1.132 ("the Ren Declaration") filed September 2, 2009, the remaining rejections of the claims under 35 USC 102(b) and 35 USC 103 based upon the Macevicz and Macevicz-II references (alone or in combination with other secondary references) are **withdrawn**. In particular, it is noted that paragraphs 22 and 28 of the Ren Declaration are considered persuasive with regard to the novelty and non-obviousness of the claims as presently amended. Accordingly, claims 40-41 as

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amended are now **allowed**. However, it is again noted that applicant's amendments have also necessitated new grounds of rejection as set forth below.

***Election/Restriction***

3. Claims 1-24 and 42-43 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 9, 2005. In light of the species election requirement applied to claim 35 (see the restriction requirement of October 11, 2005), and applicant's election of Mmel (see the reply of December 9, 2005), restriction enzymes other than Mmel also remain withdrawn from further consideration. Election was made **without** traverse in the reply filed on December 9, 2005. Although it is noted that the rejection of claim 35 under 35 USC 102(b) has been withdrawn, the claim has been rejected under 35 USC 112, first paragraph, such that rejoinder of species does not yet apply.

***Comment regarding interview and Information Disclosure Statement***

4. Applicant's summary of the interview of March 9, 2009 is noted and is accurate. Subsequent to the interview, the examiner contacted the examiner who cited the 2 references in question that lack dates. However, dates for those references remain unavailable. Because the lack of dates is due to an Office error, the examiner has considered the references and cited them on an 892 form with the notation "date not available".

***Specification***

5. The amendment filed September 2, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the descriptive information regarding a "database" that is "available at the website of New England Biolabs, Ipswich, MA" (at pages 15 and 18). This information constitutes new matter because applicant has not provided the required statement that the amendatory material is the material previously incorporated by reference and that the amendment contains no new matter. However, in the instant case, as the material is not considered essential, it is suggested that applicant merely amend the specification to employ the original web addresses in "disabled" form (i.e., by deleting the recitation "[http://](#)").

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112, second paragraph***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 25-27, 29, 31-39, 44-50, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25-27, 29, 31-38, 44-50 and 53 are indefinite over the recitation of the limitation "wherein the ditag comprises sequence information including the 5' start and 3' end of a full-length coding region of a gene" in independent claims 25-26. It is not clear

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what is encompassed by the recitation “sequence information including the 5' start and 3' end of a full-length coding region of a gene”. The specification does not employ this terminology (see also the new matter rejection below), and the prior art does not make clear what would constitute “sequence information including the 5' start and 3' end” of a gene within the context of the claimed invention. For example, what would be sufficient to meet a requirement for the “5' start” and “3' end”, and what is encompassed by the term “sequence information”? Accordingly, clarification is required to render the metes and bounds of the claims clear.

Claim 39 is indefinite over the recitation of the limitation “defining the structural region including exons and introns of the corresponding gene on the genome”. It is not clear whether this language merely requires defining the entire “structural region” of the gene (as discussed in, e.g., paragraph 346 of the published specification), wherein the region being defined includes/comprises the exons/introns of the gene (as discussed in, e.g., paragraph 147), or whether this language requires actually defining the exons/introns of the gene (a concept which is not disclosed in the originally filed specification, as indicated below). Because the meaning of the language “defining the structural region including exons and introns” is unclear, it would not be clear to one of skill in the art what actions would/would not infringe the claims. Accordingly, the claim as written is indefinite.

***Claim Rejections - 35 USC § 112, first paragraph***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 25-27, 29, 31-39, 44-50, and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Regarding independent claims 25-26 and claims dependent therefrom, it is noted that claims 25-26 have each been amended to recite the limitation "wherein the ditag comprises sequence information including the 5' start and 3' end of a full-length coding region of a gene". However, the originally filed specification does not reference or otherwise disclose "sequence information including the 5' start and 3' end of a full-length coding region of a gene". The specification does disclose a ditag that "retains the most informative features of the original nucleic acid molecule, viz. the start and the end signatures of the nucleic acid" (paragraph 73), and a ditag that "comprises the 5'-end and 3'-end of the original full-length cDNA" such that it is "representative of the structure of the full-length cDNA" (paragraph 101). However, these disclosures pertain to the presence of particular nucleic acid structures within the ditag, as opposed to "sequence information" as set forth in the claim. The term "sequence information" is not employed or defined in the specification, nor would one of skill in the art interpret the term "information" as referencing actual nucleic acid molecules/structures. Further, the specification does not reference or disclose "information including the 5' start and 3'

end"; thus, this more particular type of "sequence information" also lacks basis in the originally-filed specification.

Regarding independent claim 39, the claim as amended recites the limitation "defining the structural region including exons and introns of the corresponding gene on the genome". Although the meaning of this language is not clear, it appears that the claim may encompass an embodiment of the invention requiring defining the exons/introns of the gene. This embodiment is not supported by the originally filed specification. Applicants have disclosed defining the entire "structural region" of the gene (see, e.g., paragraph 346 of the published specification), and have disclosed that the region being defined includes/comprises the exons/introns of the gene (see, e.g., paragraph 147). However, to the extent that the claim requires defining exons/introns themselves, applicant's amendments have introduced new matter into the claims.

### ***Double patenting***

10. In view of the abandonment of co-pending application 11/045,468, the provisional obviousness-type double patenting rejection over claims of this application set forth in the prior Office action are now moot.

### ***Conclusion***

11. It is noted that applicant's reply of September 2, 2009 (on the final page of the Remarks) references "Attachment C", which was apparently intended to be a copy of accepted claims from a corresponding Japanese application. **However, the material provided as "Attachment C" is a single sheet "Official Notice of Allowance"; no**



**claim text is present.** Accordingly, if applicant wishes to provide actual claims for the examiner's review, those claims should be provided in response to this Office action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571/272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/  
Primary Examiner, Art Unit 1634